

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 13-2219

UNITED STATES ex rel. MICHAEL K. DRAKEFORD, M.D.,

Plaintiff - Appellee,

v.

TUOMEY, d/b/a Tuomey Healthcare System, Inc.,

Defendant - Appellant.

AMERICAN HOSPITAL ASSOCIATION; SOUTH CAROLINA HOSPITAL ASSOCIATION,

Amici Supporting Appellant.

Appeal from the United States District Court for the District of South Carolina, at Columbia. Matthew J. Perry, Jr., Senior District Judge; Margaret B. Seymour, Senior District Judge. (3:05-cv-02858-MBS)

Argued: October 31, 2014

Decided: July 2, 2015

Before DUNCAN, WYNN, and DIAZ, Circuit Judges.

Affirmed by published opinion. Judge Diaz wrote the majority opinion, in which Judge Duncan joined. Judge Wynn wrote a separate opinion concurring in the judgment.

ARGUED: Helgi C. Walker, GIBSON, DUNN & CRUTCHER, LLP, Washington, D.C., for Appellant. Tracy Lyle Hilmer, UNITED

STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee.
ON BRIEF: James M. Griffin, Margaret N. Fox, A. Camden Lewis, LEWIS, BABCOCK & GRIFFIN, LLP, Columbia, South Carolina; Daniel M. Mulholland III, HORTY SPRINGER & MATTERN, Pittsburgh, Pennsylvania; E. Bart Daniel, Charleston, South Carolina, for Appellant. Stuart F. Delery, Assistant Attorney General, Michael D. Granston, Michael S. Raab, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; G. Norman Acker, III, Assistant United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Raleigh, North Carolina, for Appellee. Melinda R. Hatton, Maureen D. Mudron, AMERICAN HOSPITAL ASSOCIATION, Washington, D.C.; Jessica L. Ellsworth, Amanda K. Rice, HOGAN LOVELLS US LLP, Washington, D.C., for Amici Curiae.

DIAZ, Circuit Judge:

In a qui tam action in which the government intervened, a jury determined that Tuomey Healthcare System, Inc., did not violate the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33 (2012).¹ The district court, however, vacated the jury's verdict and granted the government a new trial after concluding that it had erroneously excluded excerpts of a Tuomey executive's deposition testimony. The jury in the second trial found that Tuomey knowingly submitted 21,730 false claims to Medicare for reimbursement. The district court then entered final judgment for the government and awarded damages and civil penalties totaling \$237,454,195.

Tuomey contends that the district court erred in granting the government's motion for a new trial. Tuomey also lodges numerous other challenges to the judgment entered against it following the second trial. It argues that it is entitled to judgment as a matter of law (or, in the alternative, yet another new trial) because it did not violate the FCA. In the alternative, Tuomey asks for a new trial because the district court failed to properly instruct the jury. Finally, Tuomey

¹ Under the qui tam provisions of the FCA, a whistleblower (known as the relator) can file an action on behalf of the federal government for alleged fraud committed against the government. If the action is successful, the relator shares in the recovery.

asks us to strike the damages and civil penalties award as either improperly calculated or unconstitutional.

We conclude that the district court correctly granted the government's motion for a new trial, albeit for a reason different than that relied upon by the district court. We also reject Tuomey's claims of error following the second trial. Accordingly, we affirm the district court's judgment.

I.

A.

Tuomey is a nonprofit hospital located in Sumter, South Carolina, a small, largely rural community that is a federally-designated medically underserved area. At the time of the events leading up to this lawsuit, most of the physicians that practiced at Tuomey were not directly employed by the hospital, but instead were members of independent specialty practices.

Beginning around 2000, doctors who previously performed outpatient surgery at Tuomey began doing so in their own offices or at off-site surgery centers. The loss of this revenue stream was a source of grave concern for Tuomey because it collected substantial facility fees from patients who underwent surgery at the hospital's outpatient center. Tuomey estimated that it stood to lose \$8 to \$12 million over a thirteen-year period from the loss of fees associated with gastrointestinal procedures

alone. To stem this loss, Tuomey sought to negotiate part-time employment contracts with a number of local physicians.

In drafting the contracts, Tuomey was well aware of the constraints imposed by the Stark Law. While we discuss the provisions of that law in greater detail below, in broad terms, the statute, 42 U.S.C. § 1395nn, prohibits physicians from making referrals to entities where “[t]he referring physician . . . receives aggregate compensation . . . that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing” the designated health services. 42 C.F.R. § 411.354(c)(2)(ii) (2014). Pursuant to the Stark Law, “[a] hospital may not submit for payment a Medicare claim for services rendered pursuant to a prohibited referral.” United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394, 397–98 (4th Cir. 2012).

Beginning in 2003, Tuomey sought the advice of its longtime counsel, Nexsen Pruet, on the Stark Law implications arising from the proposed employment contracts. Nexsen Pruet in turn engaged Cejka Consulting, a national consulting firm that specialized in physician compensation, to provide an opinion concerning the commercial reasonableness and fair market value of the contracts. Tuomey also conferred with Richard Kusserow, a former Inspector General for the United States Department of

Health and Human Services, and later, with Steve Pratt, an attorney at Hall Render, a prominent healthcare law firm.

The part-time employment contracts had substantially similar terms. Each physician was paid an annual guaranteed base salary. That salary was adjusted from year to year based on the amount the physician collected from all services rendered the previous year. The bulk of the physicians' compensation was earned in the form of a productivity bonus, which paid the physicians eighty percent of the amount of their collections for that year. The physicians were also eligible for an incentive bonus of up to seven percent of their earned productivity bonus. In addition, Tuomey agreed to pay for the physicians' medical malpractice liability insurance as well as their practice group's share of employment taxes. The physicians were also allowed to participate in Tuomey's health insurance plan. Finally, Tuomey agreed to absorb each practice group's billing and collections costs.

The contracts had ten-year terms, during which physicians could maintain their private practices, but were required to perform outpatient surgical procedures exclusively at the hospital. Physicians could not own any interest in a facility located in Sumter that provided ambulatory surgery services, save for a less-than-two-percent interest in a publicly traded company that provided such services. The physicians also agreed

not to perform outpatient surgical procedures within a thirty-mile radius of the hospital for two years after the expiration or termination of the contracts.

Tuomey ultimately entered into part-time employment contracts with nineteen physicians. Tuomey, however, was unable to reach an agreement with Dr. Michael Drakeford, an orthopedic surgeon. Drakeford believed that the proposed contracts violated the Stark Law because the physicians were being paid in excess of their collections. He contended that the compensation package did not reflect fair market value, and thus the government would view it as an unlawful payment for the doctor's facility-fee-generating referrals.

To address Drakeford's concerns, Tuomey suggested a joint venture as an alternative business arrangement, whereby "doctors would become investors . . . in . . . a management company that would provide day-to-day management of the outpatient surgery center," J.A. 3268, and both Tuomey and its co-investors would "receive payments based on that management [structure]." J.A. 2036. Drakeford, however, declined that option.

Unable to break the stalemate in their negotiations, in May 2005, Tuomey and Drakeford sought the advice of Kevin McAnaney, an attorney in private practice with expertise in the Stark Law. McAnaney had formerly served as the Chief of the Industry Guidance Branch of the United States Department of Health and

Human Services Office of Counsel to the Inspector General. In that position, McAnaney wrote a "substantial portion" of the regulations implementing the Stark Law. J.A. 2026.

McAnaney advised the parties that the proposed employment contracts raised significant "red flags" under the Stark Law.² J.A. 2054. In particular, Tuomey would have serious difficulty persuading the government that the contracts did not compensate the physicians in excess of fair market value. Such a contention, said McAnaney, would not pass the "red face test." J.A. 2055. McAnaney also warned Tuomey that the contracts presented "an easy case to prosecute" for the government. J.A. 2078.

Drakeford ultimately declined to enter into a contract with Tuomey. He later sued the hospital under the qui tam provisions of the FCA, alleging that because the part-time employment contracts violated the Stark Law, Tuomey had knowingly submitted false claims for payment to Medicare. As was its right, the government intervened in the action and filed additional claims

² According to McAnaney, the joint venture alternative raised separate concerns under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which bars "the payment of remuneration for the purpose of inducing the purchase of health care covered by any federal health care insurance program." Michael K. Loucks & Carol C. Lam, Prosecuting and Defending Health Care Fraud Cases 233 (2d ed. 2010).

seeking equitable relief for payments made under mistake of fact and unjust enrichment theories.

B.

At the first trial, Tuomey argued that McAnaney's testimony and related opinions regarding the contracts should be excluded as an offer to compromise or settle under Federal Rule of Evidence 408 because McAnaney was mediating a dispute between Tuomey and Drakeford. Alternatively, Tuomey contended that because McAnaney was hired jointly by Tuomey and Drakeford, he owed a duty of loyalty to both clients that precluded him from testifying. The district court sustained Tuomey's objection, although it did not articulate the ground for its ruling.

Tuomey also objected to the government's attempt to admit excerpts from the deposition testimony of Gregg Martin, Tuomey's Senior Vice President and Chief Operating Officer. Tuomey argued that the deposition testimony should be excluded because it contained Martin's recollections of a discussion he had with Tuomey's counsel concerning McAnaney's opinions regarding the employment contracts. According to Tuomey, the testimony was merely a "back doorway to get in Mr. McAnaney's opinions." J.A. 808. The government countered that the deposition testimony was admissible to show Tuomey's state of mind and intent to violate the Stark Law. The district court again sustained Tuomey's objection.

The jury returned a verdict finding that, while Tuomey had violated the Stark Law, it had not violated the FCA. The government filed a post-verdict motion for judgment on its equitable claims. It also moved for judgment as a matter of law under Federal Rule of Civil Procedure 50 on the FCA claim, or alternatively for a new trial under Rule 59 because of the district court's decision to exclude McAnaney's testimony and opinions, as well as the Martin deposition excerpts.

The district court denied the government's motion for judgment as a matter of law. But the court agreed that it had committed "a substantial error" by excluding the Martin deposition excerpts. J.A. 1296. It therefore granted the government's motion for a new trial. Notably, the district court's decision was based solely on its error in excluding the Martin deposition excerpts.

While the government asked for a new trial only on the knowledge element of the FCA claim, the district court granted a new trial as to the entirety of the claim. Notwithstanding the court's decision to grant a new trial on the FCA claim, the district court entered judgment for the government on its equitable claims based on the jury's finding of a Stark Law violation, and ordered Tuomey to pay damages in the amount of \$44,888,651 plus pre- and post-judgment interest.

On appeal, we vacated the judgment, concluding that the jury's finding of a Stark Law violation was a common factual issue necessary to the resolution of both the equitable claims and the FCA claim.³ Yet, because the district court rendered the jury's verdict finding a Stark Law violation a "legal nullity" when it granted the government's motion for a new trial, we held that the court deprived Tuomey of its Seventh Amendment right to a jury trial by entering judgment on the equitable claims. Drakeford, 675 F.3d at 405. We remanded the case for a new trial as to all claims.

While the case was on appeal, the presiding judge passed away. At the second trial, the new presiding judge allowed the government to introduce the previously excluded Martin deposition testimony, and also allowed McAnaney to testify. The jury found that Tuomey violated both the Stark Law and the FCA. It further found that Tuomey had submitted 21,730 false claims to Medicare with a total value of \$39,313,065. The district court trebled the actual damages and assessed an additional civil penalty, both actions required by the FCA. 31 U.S.C. § 3729(a)(1). From the resulting judgment of \$237,454,195, Tuomey appeals.

³ Tuomey also sought leave to pursue an interlocutory appeal of the district court's order granting a new trial on the FCA claim. We denied that motion.

II.

A.

Tuomey's appeal presents these issues: First, did the district court err in granting the government's motion for a new trial on the FCA claim? If not, did the district court err in (1) denying Tuomey's motion for judgment as a matter of law (or, in the alternative, for yet another new trial) following the second trial; and (2) awarding damages and penalties against Tuomey based on the jury's finding of an FCA violation? We address each issue in turn, but first provide a general overview of the Stark Law.

B.

The Stark Law is intended to prevent "overutilization of services by physicians who [stand] to profit from referring patients to facilities or entities in which they [have] a financial interest." Drakeford, 675 F.3d at 397. The statute prohibits a physician from making a referral to an entity, such as a hospital, with which he or she has a financial relationship, for the furnishing of designated health services. 42 U.S.C. § 1395nn(a)(1). If the physician makes such a referral, the hospital may not submit a bill for reimbursement to Medicare. Id. § 1395nn(a)(1)(B). Similarly, the government may not make any payment for a designated health service provided in violation of the Stark Law. Id. § 1395nn(g)(1). If

a person collects any payment for a service billed in violation of the Stark Law, "the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected." Id. § 1395nn(g)(2).⁴

Inpatient and outpatient hospital services are considered designated health services under the law. Id. § 1395nn(h)(6). A referral includes "the request by a physician for the item or service." Id. § 1395nn(h)(5)(A). A referral does not include "any designated health service personally performed or provided by the referring physician." 42 C.F.R. § 411.351. However, there is a referral when the hospital bills a "facility fee" (also known as a "facility component" or "technical component") "in connection with the personally performed service." Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 941 (Jan. 4, 2001); see also Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16063 (Mar. 26, 2004).

⁴ Because the Stark Law does not create its own right of action, the government in this case sought relief under the FCA, which provides a right of action with respect to false claims submitted for Medicare reimbursement. See Drakeford, 675 F.3d at 396 & n.2.

A financial relationship constitutes a prohibited "indirect compensation arrangement," if (1) "there exists an unbroken chain of any number . . . of persons or entities that have financial relationships . . . between them," (2) "[t]he referring physician . . . receives aggregate compensation . . . that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing" the designated health services, and (3) the entity has knowledge that the compensation so varies. 42 C.F.R. § 411.354(c)(2); see also Drakeford, 675 F.3d at 408 ("[C]ompensation arrangements that take into account anticipated referrals . . . implicate the volume or value standard."). The statute, however, does not bar indirect compensation arrangements where: (1) the referring physician is compensated at fair market value for "services and items actually provided"; (2) the compensation arrangement is "not determined in any manner that takes into account the volume or value of referrals"; (3) the compensation arrangement is "commercially reasonable"; and (4) the compensation arrangement does not run afoul of any other federal or state law. 42 C.F.R. § 411.357(p); Drakeford, 675 F.3d at 398.

Once a relator or the government has established the elements of a Stark Law violation, it becomes the defendant's burden to show that the indirect compensation arrangement

exception shields it from liability. See United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009).

C.

We first address the district court's decision to grant the government a new trial on the FCA claim. The government pressed two grounds in support of its motion. First, it argued that the district court erred by excluding McAnaney's testimony, along with all evidence containing the views he expressed to the parties on the potential Stark Law liability surrounding the contracts. Second, the government argued that the district court erroneously excluded the Martin deposition excerpts. While the district court granted a new trial on the latter ground, we instead affirm the district court on the basis of its more glaring error, the exclusion of McAnaney's testimony and related evidence.

1.

We review a district court's decision to grant a new trial for abuse of discretion. Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998). We apply the same standard to the district court's decision to exclude evidence. Buckley v. Mukasey, 538 F.3d 306, 317 (4th Cir. 2008). "By definition, a district court abuses its discretion when it makes an error of law." RZS Holdings AVV v. PDVSA Petroleo S.A., 506 F.3d 350, 356 (4th Cir. 2007). Even so, we may reverse a district court

only if its evidentiary error affects a party's substantial rights. Buckley, 538 F.3d at 317. And, of course, we may affirm a district court's ruling on any ground apparent in the record. Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992).

2.

We believe that the district court abused its discretion in granting a new trial on the ground that it had improperly excluded the Martin deposition excerpts. Even if the district court should not have excluded this evidence in the first instance, an evidentiary error is harmless when it does not affect a party's substantial rights--in this case, whether it can be said with a high probability that the error did not affect the judgment. Taylor v. Va. Union Univ., 193 F.3d 219, 235 (4th Cir. 1999) (en banc), abrogated on other grounds by Desert Palace, Inc. v. Costa, 539 U.S. 90 (2003); Daskarolis v. Firestone Tire & Rubber Co., 651 F.2d 937, 942 (4th Cir. 1981) (noting that even if the district court believed that it had excluded admissible evidence, the erroneous exclusion could not be grounds for a new trial because it did not affect the substantial rights of the parties). The district court made no effort to assess the alleged error under this stringent harmless error standard. Furthermore, because the exclusion of the Martin deposition testimony was, in fact, a harmless error, the

district court abused its discretion in granting a new trial on this ground.

In its motion for a new trial, the government argued that Martin's testimony was necessary evidence supporting the scienter element of its FCA claim. Specifically, the government contended that Martin, Tuomey's agent, received and ignored McAnaney's warnings that the part-time employment contracts raised significant Stark Law compliance issues. Thus, says the government, the evidence would have demonstrated Tuomey's reckless disregard of the legal minefield that it was traversing. We think, however, that the probative value of this particular evidence is weak at best, and excluding it did not negatively affect the government's substantial rights.

The deposition excerpts predominantly focus on Martin's recollection of a discussion he had with Tuomey's lawyer, Tim Hewson. Hewson recounted to Martin the details of a conference call between Hewson, McAnaney, and Drakeford's lawyer, Greg Smith.⁵ Specifically, Hewson told Martin that McAnaney had Stark Law compliance concerns with both the proposed part-time

⁵ Hewson was likely recounting the details of two separate conference calls. The first call was between McAnaney, Smith, and Hewson and covered the part-time employment contracts. The following day, Steve Pratt joined those three for a second call focusing on the joint venture arrangement. When asked if he was aware that there were two separate conference calls, Martin responded that he did not "remember for sure." J.A. 105.

employment contracts as well as the joint venture arrangement (which Martin referred to as the "under arrangement"). However, Martin was unable to remember specifics about the conversation, and often confused McAnaney's concerns with issues raised by Steve Pratt.

Martin did vaguely recall that Hewson had told him that McAnaney said the proposed arrangements would raise "red flags" with the government. J.A. 104-05. Yet, Martin could not remember whether McAnaney's warnings were particular to the part-time employment contracts, the joint venture arrangement, or both. Indeed, in Martin's recollection it was hard to "separate the two." J.A. 107. To the extent that Martin could distinguish the two proposed arrangements, he recalled being warned of greater problems with the joint venture arrangement.

With respect to McAnaney's concerns about the employment contracts, Martin had a vague recollection of some issues related to fair market value, but was unable to offer more detail. Ultimately, Martin acknowledged that there was a "difference of opinion" between McAnaney and Hewson, but decided to trust Hewson's opinion that the contracts posed no Stark Law concerns. J.A. 111.

That Martin's deposition testimony was hazy is not at all surprising, given that he was being asked to recall--nearly four years after the fact--the substance of a conversation with

Tuomey's lawyer, who himself was recalling an earlier conference call with McAnaney. Standing alone, we fail to see how the government was substantially prejudiced by the district court's decision to exclude this evidence. Thus, we hold that the district court abused its discretion in relying on this ground to grant the government's motion for a new trial.

3.

Nonetheless, we affirm the district court's order granting a new trial on the alternative ground urged by the government--that it was prejudiced by the exclusion of McAnaney's testimony and other related evidence of his warnings to Tuomey regarding the legal peril that the employment contracts posed.⁶ To make its case that Tuomey "knowingly" submitted false claims under the FCA, the government needed to show that Tuomey knew that there was a substantial risk that the contracts violated the Stark Law, and was nonetheless deliberately ignorant of, or recklessly disregarded that risk. In our view, McAnaney's

⁶ Tuomey says that we may not affirm on this alternative ground because the government's brief never asked us to do so. But this assertion splits the thinnest of hairs. While perhaps the government could have been more direct in its brief, it clearly alerted us (and Tuomey) that there was an alternate ground for affirming the district court. See Appellee's Br. at 82 ("[The] new trial ruling was correct not only because of the exclusion of Martin's testimony, but also because the exclusion of McAnaney's testimony and related evidence was clearly erroneous and affected the substantial rights of the government.").

testimony was a relevant, and indeed essential, component of the government's evidence on that element, and Tuomey offered no good reason why the jury should not hear it.

The district court has now presided over two trials in this case, with strikingly disparate results. In the first trial, the jury did not hear from McAnaney and found for Tuomey on the FCA claim. When the case was retried, McAnaney was allowed to testify and the jury found for the government. Coincidence? We think not. Rather, we believe that these results bespeak the importance of what the jury in the first trial was not allowed to consider.

And this is so even while acknowledging that McAnaney was a looming presence throughout the first trial. For example, the jury heard audio of a Tuomey board meeting, where a board member mentioned that McAnaney had voiced concerns with the part-time employment contracts. Left unsaid, however, was the precise nature of those concerns or the weight and seriousness that McAnaney attached to them. The jury also knew that Hewson (Tuomey's counsel at Nexson Pruet) was generally aware of McAnaney's views on the employment contracts, but that he dismissed them as not credible because, in his view, Drakeford was deliberately seeking to cherry pick a legal opinion that would undermine the entire deal.

The jury was also aware that Drakeford⁷ wrote to Tuomey's board summarizing McAnaney's opinions. The district court, however, excluded Drakeford's letter, although it did allow the jury to consider the board's response wherein it summarily rejected Drakeford's unspecified objections. Finally, the jury heard that Tuomey refused to allow McAnaney to prepare a written opinion discussing his concerns regarding the contracts, and subsequently terminated McAnaney's engagement altogether on September 2, 2005.

While certainly not insubstantial, the sum of the evidence at the first trial regarding McAnaney was that Tuomey (1) was aware that McAnaney had unspecified concerns about the employment contracts; (2) refused to allow McAnaney to relay his concerns in writing; and (3) later terminated McAnaney's joint representation. Yet, under the FCA, the government had to prove that Tuomey knew of, was deliberately ignorant of, or recklessly disregarded the falsity of its claims (i.e. that its claims violated the Stark Law). We think that McAnaney's specific warnings to Tuomey regarding the dangers posed by the contracts were critical to making this showing.

McAnaney warned Tuomey that procuring fair market valuations, by itself, was not conclusive of the accuracy of the

⁷ Drakeford was not called as a witness at either trial.

valuation. He emphasized that it would be very hard to convince the government that a contract that paid physicians "substantially above even their collections, much less their collections minus expenses," would constitute fair market value. J.A. 2053. According to McAnaney, compensation arrangements under which the contracting physicians are paid in excess of their collections were "basically a red flag to the government." Id. He noted that similar cases had previously been prosecuted before, although all of them ultimately settled.

McAnaney also pointed out that the ten-year term of the contracts, combined with the thirty-mile, two-year noncompete provision would reinforce the government's view that Tuomey was "paying [the physicians] above fair market value for referrals." J.A. 2055. He concluded that the contracts did not pass the "red face test," and warned that the government would find this "an easy case to prosecute." J.A. 2055, 2078.

We think the importance of McAnaney's testimony to the government's case is self-evident. Indeed, it is difficult to imagine any more probative and compelling evidence regarding Tuomey's intent than the testimony of a lawyer hired by Tuomey, who was an undisputed subject matter expert on the intricacies of the Stark Law, and who warned Tuomey in graphic detail of the

thin legal ice on which it was treading with respect to the employment contracts.⁸

4.

Tuomey urges, however, that McAnaney's testimony and other evidence containing his views were properly excluded under Federal Rule of Evidence 408. That rule, however, mandates the exclusion of evidence relating to offers to compromise or settle disputed claims if the evidence is being offered to prove liability on the claim. Bituminous Constr., Inc. v. Rucker Enters., Inc., 816 F.2d 965, 968 (4th Cir. 1987). We are not persuaded that McAnaney was retained to help Drakeford and Tuomey compromise or settle a disputed claim. Rather, the record unambiguously shows that Drakeford and Tuomey hired McAnaney to advise them of the Stark Law risks posed by the employment contracts. As a result, Rule 408 does not support the district court's decision to exclude McAnaney's testimony.⁹

⁸ We note that Tuomey waived the attorney-client privilege with respect to its communications with McAnaney when it asserted the advice-of-counsel defense. See Rhone-Poulenc Rorer Inc. v. Home Indem. Co., 32 F.3d 851, 863 (3d Cir. 1994) ("A defendant may . . . waive [attorney-client] privilege by asserting reliance on the advice of counsel as an affirmative defense.").

⁹ In any event, as our concurring colleague ably explains, even assuming that McAnaney's testimony would ordinarily be excludable under Rule 408, Tuomey nonetheless opened the door to its admission by raising the advice-of-counsel defense.

See ICAP, Inc. v. Global Digital Satellite Sys., Inc., 225 F.3d 654, 2000 WL 1049854, at *3 (4th Cir. 2000) (unpublished table opinion) (finding Rule 408 inapplicable where the parties' communications involved contract negotiations rather than settlement negotiations).

Nor do we find merit in Tuomey's objection based on McAnaney's supposed duty of loyalty to his clients. At trial, Tuomey never suggested which evidentiary rule supported exclusion on this ground, although it now characterizes this argument as a claim for exclusion under Rule 403. That rule of course allows a district court to exclude relevant evidence, but only "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Left unsaid by Tuomey is precisely how the probative value of McAnaney's compelling testimony was substantially outweighed by the countervailing factors set out in Rule 403.

In sum, Tuomey has offered no good reason why the jury in the first trial was not allowed to hear from McAnaney. And we agree with the government that this evidence was critical to its ability to satisfy its burden to prove that Tuomey acted with the requisite intent under the FCA. We therefore affirm the district court's order granting a new trial on the FCA claim.

III.

We turn now to Tuomey's challenges to the judgment entered following the second trial. Tuomey asks for judgment as a matter of law because a reasonable jury could not have found that (1) the part-time employment contracts violated the Stark Law, or (2) Tuomey knowingly submitted false claims. Alternatively, Tuomey asks for a new trial because of the district court's refusal to tender certain jury instructions.

A.

We review the district court's denial of Tuomey's motion for judgment as a matter of law *de novo*. Austin v. Paramount Parks, Inc., 195 F.3d 715, 727 (4th Cir. 1999). We "view all the evidence in the light most favorable to the prevailing party and draw all reasonable inferences in [its] favor." Konkel v. Bob Evans Farms Inc., 165 F.3d 275, 279 (4th Cir. 1999). We will reverse the district court if a reasonable jury could rule only in favor of the moving party. Dennis v. Columbia Collecton Med. Ctr., Inc., 290 F.3d 639, 645 (4th Cir. 2002) ("[I]f reasonable minds could differ, we must affirm.").

1.

Tuomey argues that it is entitled to judgment as a matter of law because the contracts between it and the physicians did not run afoul of the Stark Law. As we explain, however, a reasonable jury could find that Tuomey violated the Stark Law

when it paid aggregate compensation to physicians that varied with or took into account the volume or value of actual or anticipated referrals to Tuomey.

To begin with, we note that the Stark Law's "volume or value" standard can be implicated when aggregate compensation varies with the volume or value of referrals, or otherwise takes into account the volume or value of referrals. 42 C.F.R. § 411.354(c)(2)(ii). That is precisely what the district court directed the jury in the second trial to assess. Tuomey insists, however, that our earlier opinion in this case foreclosed the jury's consideration of whether the contracts varied with the volume or value of referrals. Instead, says Tuomey, the only question that should have been put to the jury was "whether the contracts, on their face, took into account the value or volume of anticipated referrals." Drakeford, 675 F.3d at 409.

We disagree. The district court properly understood that the jury was entitled to pass on the contracts as they were actually implemented by the parties. We said as much in our earlier opinion, where

we emphasize[d] that our holding . . . [was] limited to the issues we specifically address[ed]. On remand, a jury must determine, in light of our holding, whether the aggregate compensation received by the physicians under the contracts varied with, or took into account, the volume or value of the facility component referrals.

Id. at 409 n.26 (emphasis added).

A reasonable jury could have found that Tuomey's contracts in fact compensated the physicians in a manner that varied with the volume or value of referrals. There are two different components of the physicians' compensation that we believe so varied. First, each year, the physicians were paid a base salary that was adjusted upward or downward depending on their collections from the prior year. In addition, the physicians received the bulk of their compensation in the form of a productivity bonus, pegged at eighty percent of the amount of their collections.

As Tuomey concedes, "the aggregate compensation received by the physicians under the Contracts was based solely on collections for personally performed professional services." Appellant's Br. at 42. And as we noted in our earlier opinion, there are referrals here, "consisting of the facility component of the physicians' personally performed services, and the resulting facility fee billed by Tuomey based upon that component." Drakeford, 675 F.3d at 407. In sum, the more procedures the physicians performed at the hospital, the more facility fees Tuomey collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses.

The nature of this arrangement was confirmed by Tuomey's former Chief Financial Officer, William Paul Johnson, who admitted "that every time one of the 19 physicians . . . did a legitimate procedure on a Medicare patient at the hospital pursuant to the part-time agreement[,] the doctor [got] more money," and "the hospital also got more money." J.A. 2012. We thus think it plain that a reasonable jury could find that the physicians' compensation varied with the volume or value of actual referrals. The district court did not err in denying Tuomey's motion for judgment as a matter of law on this ground.¹⁰

¹⁰ We are not persuaded by Tuomey's reliance on commentary promulgated by the Centers for Medicare & Medicaid Services as it developed implementing regulations for the Stark Law. Tuomey points to a portion of the commentary wherein the agency states that the "fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)." 69 Fed. Reg. at 16089. But this statement deals only with a productivity bonus based on the fair market value of the work personally performed by a physician--it says nothing about the propriety of varying a physician's base salary based on the volume or value of referrals.

In any case, the commentary regarding productivity bonuses appears under a section of the regulations that specifically addresses comments related to the exception for bona fide employment relationships. This exception covers circumstances where there is a meaningful administrative relationship between the physician and the hospital. The jury was instructed on this exception at trial, and rejected it. Tuomey does not quarrel with that aspect of the jury's verdict; rather it contends that the commentary applies irrespective of whether a bona fide employment relationship actually exists. Nothing in the statute or the regulations, however, supports this notion.

2.

Tuomey next argues that the district court erred in not granting its motion for judgment as a matter of law because it did not knowingly violate the FCA. Specifically, Tuomey claims that because it reasonably relied on the advice of counsel, no reasonable jury could find that Tuomey possessed the requisite intent to violate the FCA. Because the record here is replete with evidence indicating that Tuomey shopped for legal opinions approving of the employment contracts, while ignoring negative assessments, we disagree.

The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to an officer or employee of the United States Government. 31 U.S.C. § 3729(a)(1)(A), (b)(2)(A)(i). Under the Act, the term "knowingly" means that a person, with respect to information contained in a claim, (1) "has actual knowledge of the information;" (2) "acts in deliberate ignorance of the truth or falsity of the information;" or (3) "acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1). The purpose of the FCA's scienter requirement is to avoid punishing "honest mistakes or incorrect claims submitted through mere negligence." United States ex rel. Owens v. First Kuwaiti

Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir. 2010) (internal quotation marks omitted).

The record evidence provides ample support for the jury's verdict as to Tuomey's intent. Indeed, McAnaney's testimony, summarized above, is alone sufficient to sweep aside Tuomey's claim of error.¹¹ We agree with the district court's conclusion that "a reasonable jury could have found that Tuomey possessed the requisite scienter once it determined to disregard McAnaney's remarks." J.A. 4055-56. A reasonable jury could indeed be troubled by Tuomey's seeming inaction in the face of McAnaney's warnings, particularly given Tuomey's aggressive efforts to avoid hearing precisely what McAnaney had to say regarding the contracts.

Nonetheless, a defendant may avoid liability under the FCA if it can show that it acted in good faith on the advice of counsel. Cf. United States v. Painter, 314 F.2d 939, 943 (4th Cir. 1963) (holding, in a case involving fraud, that "[i]f in good faith reliance upon legal advice given him by a lawyer to whom he has made full disclosure of the facts, one engages in a

¹¹ We note also that the jury at the second trial considered the deposition testimony of Tuomey executive Gregg Martin. While this evidence is (for reasons we have explained) not overly compelling in isolation, it is not without some value in showing that Tuomey was aware that its proposed contracts raised Stark Law concerns.

course of conduct later found to be illegal, the trier of fact may in appropriate circumstances conclude the conduct was innocent because 'the guilty mind' was absent"). However, "consultation with a lawyer confers no automatic immunity from the legal consequences of conscious fraud." Id. at 943. Rather, to establish the advice-of-counsel defense, the defendant must show the "(a) full disclosure of all pertinent facts to [counsel], and (b) good faith reliance on [counsel's] advice." United States v. Butler, 211 F.3d 826, 833 (4th Cir. 2000) (internal quotation marks omitted).

Tuomey contends that it provided full and accurate information regarding the proposed employment contracts to Hewson, who in turn advised Tuomey that the contracts did not run afoul of the Stark Law. But as the government aptly notes, "[i]n determining whether Tuomey reasonably relied on the advice of its counsel, the jury was entitled to consider all the advice given to it by any source." Appellee's Br. at 53.

In denying Tuomey's post-trial motions, the district court noted--and we agree--that a reasonable jury could have concluded that Tuomey was, after September 2005, no longer acting in good faith reliance on the advice of its counsel when it refused to give full consideration to McAnaney's negative assessment of the part-time employment contracts and terminated his

representation.¹² Tuomey defends its dismissal of McAnaney's warnings by claiming that his opinion was tainted by undue influence exerted by Drakeford and his counsel. But there was evidence before the jury suggesting that Tuomey also tried to procure a favorable opinion from McAnaney. Indeed, Tuomey's counsel admitted that he was trying "to steer McAnaney towards [Tuomey's] desired outcome" and that Tuomey needed to "continue playing along and influence the outcome of the game as best we can." J.A. 4482. Thus, a reasonable jury could conclude that Tuomey ignored McAnaney because it simply did not like what he had to say.

Tuomey points to the fact that it retained Steve Pratt, a prominent healthcare lawyer, and Richard Kusserow, former Inspector General at the United States Department of Health and Human Services, as further evidence that it acted in good faith and did not ignore McAnaney's warnings. Pratt rendered two

¹² The government contended that Tuomey submitted 25,973 total claims for payment to Medicare between fiscal years 2005 and 2009. The government's evidence on this point consisted of a summary chart detailing the number of claims filed by Tuomey in each fiscal year. It appears, however, that the jury subtracted the 4,243 claims that Tuomey submitted in fiscal year 2005 (running from October 1, 2004 to September 30, 2005) from the government's number. From this, the district court surmised that the jury resolved to hold Tuomey responsible for those claims filed beginning in fiscal year 2006 (that is, on or after October 1, 2005) given that they were filed after Tuomey terminated McAnaney's joint representation on September 2, 2005. We think this is an entirely reasonable view of the evidence.

opinions that generally approved of the employment contracts. But he did so without being told of McAnaney's unfavorable assessment, even though Tuomey had that information available to it at the time. In addition, Pratt reviewed and relied on the view of Tuomey's fair-market-value consultant that the employment contracts would compensate the physicians at fair market value, but he did not consider how the consultant arrived at its opinion. Nor did he know how much the doctors earned prior to entering into the contracts, or that the hospital stood to lose \$1.5-2 million a year, not taking into account facility fees, by compensating the physicians above their collections. We thus think it entirely reasonable for a jury to look skeptically on Pratt's favorable advice regarding the contracts.

The same can be said of the Kusserow's advice. Kusserow-- who was called by the government to rebut Tuomey's advice-of-counsel defense--advised Tuomey regarding the employment contracts about eighteen months before the parties retained McAnaney. As was the case with Pratt, he received no information regarding the fair market value of the employment contracts, information that Kusserow considered vital "to be able to do a full Stark analysis of [the proposed contracts]." J.A. 1676. And although Kusserow did say in a letter to Tuomey's counsel that he did not believe the contracts presented "significant Stark issues," J.A. 1675, he hedged considerably on

that view because of "potentially troubling issues related to the productivity and [incentive bonus provisions in the contracts] that have not been fully addressed." J.A. 1677.

As the district court observed, "the jury evidently rejected Tuomey's advice of counsel defense" as of the date that Tuomey received McAnaney's warnings, "grounded on the fact that the jury excluded damages from [before the termination of McAnaney's engagement] in making its determination" of the civil penalty and damages. J.A. 4055. Thus, while Kusserow's advice was certainly relevant to Tuomey's advice-of-counsel defense, a reasonable jury could have determined that McAnaney's warnings (and Tuomey's subsequent inaction) were far more probative on the issue.

In sum, viewing the evidence in the light most favorable to the government, we have no cause to upset the jury's reasoned verdict that Tuomey violated the FCA.

B.

Next, Tuomey raises several challenges to the district court's jury instructions. We review a district court's "decision to give (or not give) a jury instruction and the content of an instruction . . . for abuse of discretion." United States v. Russell, 971 F.2d 1098, 1107 (4th Cir. 1992). Our task is to determine "whether the instructions[,] construed as a whole, and in light of the whole record, adequately

informed the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party.” Spell v. McDaniel, 824 F.2d 1380, 1395 (4th Cir. 1987). We will reverse the district court’s decision not to give a party’s proposed instruction “only when the requested instruction (1) was correct; (2) was not substantially covered by the court’s charge to the jury; and (3) dealt with some point in the trial so important, that failure to give the requested instruction seriously impaired that party’s ability to make its case.” Noel v. Artson, 641 F.3d 580, 586 (4th Cir. 2011) (internal quotation marks omitted).¹³

1.

First, Tuomey urges us to grant it a new trial because the district court failed to give jury instructions consistent with our analysis in the first appeal. Specifically, Tuomey claims that the district court ignored our admonition that “the question, which should properly be put to a jury, is whether the contracts, on their face, took into account the value or volume of anticipated referrals.” Drakeford, 675 F.3d at 409. According to Tuomey, the district court’s failure to so instruct the jury erroneously permitted the jury to consider extrinsic

¹³ Because two of Tuomey’s challenges to the instructions address the proper calculation of damages, we address them separately infra at Sections IV.A.1, and IV.B.

evidence of intent in determining whether the physicians' compensation took into account the volume or value of referrals.

As the district court correctly determined, however, we did not mean to limit the government's ability to present evidence as to Tuomey's intent to violate the FCA. Rather, we sought to emphasize that the government could not rely on such evidence alone to show a violation. See id. at 409 n.25 ("We agree with United States ex rel. Villafane v. Solinger, 543 F. Supp. 2d 678, 693 (W.D. Ky. 2008) that intent alone does not create a violation. However, that does not aid Tuomey if the jury determines that the contracts took into account the volume or value of anticipated referrals."). Thus, the district court did not err in declining to give this instruction.

2.

Tuomey next argues that the district court erred in not separately instructing the jury on the knowledge element in the Stark Law regulations' definition of an indirect compensation arrangement. As Tuomey correctly notes, the Stark Law requires that "[t]he entity furnishing [designated health services must] ha[ve] actual knowledge of, or act[] in reckless disregard or deliberate ignorance of, the fact that the referring physician . . . receives aggregate compensation that varies with, or takes into account, the volume or value of referrals." 42 C.F.R. § 411.354(c)(2)(iii).

Here, however, the district court instructed the jury that Tuomey would have acted knowingly under the FCA if it "realized what it was doing and was aware of the nature of its conduct and did not act through ignorance, mistake or accident." J.A. 3942-43. Given that a jury found Tuomey possessed the requisite scienter under the FCA, it necessarily also found Tuomey knew that its contracts varied with or took into account referrals. Therefore, the district court's error (if any) in not separately instructing the jury as to the knowledge component of the Stark Law was harmless.

3.

Third, Tuomey argues that the district court erred by refusing to charge the jury that claims based upon differences of interpretation of disputed legal questions are not false under the FCA. For this proposition, it cites to our decision in United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 377 (4th Cir. 2008), in which we said as much. However, we also held there that for a claim to be "false" under the FCA, "the statement or conduct alleged must represent an objective falsehood." Id. at 376.

When submitting its claims to the government, Tuomey was required to certify its compliance with the Stark Law. See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997) ("[W]here the government has

conditioned payment of a claim upon a claimant's certification of compliance with . . . a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation."); United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153, 158-59 (D.D.C. 2008). Here, Tuomey either complied with the Stark Law or it didn't. This is an objective inquiry. And the jury found that Tuomey, in fact, violated the Stark Law. As a result, Tuomey's certification that it complied with the Stark Law was false. The subjective inquiry--whether Tuomey knew that its claims were in violation of the Stark Law--is covered under the knowledge element.¹⁴ Therefore, the district court did not err in refusing to give this instruction.

4.

For their last jury instruction challenge, Tuomey contends that the district court erred by failing to instruct the jury that Tuomey was entitled to rely on legal advice even if it turned out to be wrong. However, the district court instructed

¹⁴ In Wilson, there was no either/or proposition of the kind present here. Rather, in that case, the relators contended that the disputed statement was false because the defendant "agreed to [certain conditions] in the contract even though it knew it would not, and later did not, abide by those terms." Wilson, 525 F.3d at 377. As we explained, the relators' assertion did not rest on an objective falsehood, "but rather on Relators' subjective interpretation of [the defendant's] contractual duties." Id.

the jury that knowledge does not include actions taken "through ignorance, mistake or accident." J.A. 3943. It later emphasized that the jury could not conclude that Tuomey had knowledge "from proof of mistake, negligence, carelessness or a belief in an inaccurate proposition." Id. (emphasis added). Because the import of Tuomey's proposed charge was covered by the district court's instructions, we reject Tuomey's claim of error.

IV.

Finally, Tuomey makes several challenges to the \$237,454,195 judgment entered against it. First, it argues that the district court improperly calculated the civil penalty. Next, it claims that the district court used the incorrect measure of actual damages. Finally, it brings constitutional challenges to the award under the Fifth and Eighth Amendments.

A defendant found liable under the FCA must pay the government "a civil penalty of" not less than \$5,500 and not more than \$11,000 "plus 3 times the amount of damages which the Government sustains because of that person." 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9).¹⁵ In this case, the jury

¹⁵ The FCA sets the civil penalty range at \$5,000 to \$10,000, but includes a provision that adjusts the range for inflation.

found that Tuomey had submitted 21,730 false claims, for which it awarded actual damages of \$39,313,065, which the district court trebled. The district court then added a civil penalty of \$119,515,000 to that sum, which it calculated by multiplying the number of false claims by the \$5,500 statutory minimum penalty.

Ordinary, we review a court's calculation of damages for clear error. Universal Furniture Int'l, Inc. v. Collezione Europa USA, Inc., 618 F.3d 417, 427 (4th Cir. 2010). However, to the extent the claim is that the calculations are influenced by legal error, our review is de novo. Id. Likewise, the constitutionality of a damages award is a legal question that we review de novo. See Cooper Indus., Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 436 (2001).

A.

1.

According to Tuomey, the civil penalty assessed was improperly inflated because the jury was permitted to take into account both inpatient and outpatient procedures performed by the contracting physicians. Instead, relying on our earlier opinion in this case, Tuomey claims that the only relevant claims "were those Tuomey 'presented, or caused to be presented, to Medicare and Medicaid for payment of facility fees generated as a result of outpatient procedures performed pursuant to the

contracts." Appellant's Br. at 54 (alterations omitted) (quoting Drakeford, 675 F.3d at 399). Tuomey is incorrect.

It is true that the contracts solely addressed compensation for outpatient procedures. That is, the physicians' collections (which form the basis for both their base salaries and their productivity bonuses) do not account for the volume or value of inpatient procedures performed. Tuomey, however, takes out of context language from our earlier opinion recognizing this fact to suggest that we commanded that the relevant claims be limited to those seeking payment for outpatient procedures. We said nothing of the sort.

If a physician has a financial relationship with a hospital, then the Stark Law prohibits the physician from making any referral to that hospital for the furnishing of designated health services. E.g., United States ex rel. Bartlett v. Ashcroft, 39 F. Supp. 3d 656, 669 (W.D. Pa. 2014) ("Because a 'compensation arrangement' existed between Physician Defendants and [the] Hospital, the Stark [Law] prohibited Physician Defendants from making any patient referrals to [the] Hospital for designated health services." (emphasis added)). Inpatient hospital services are designated health services. 42 U.S.C. § 1395nn(h)(6). And a referral includes "the request or establishment of a plan of care by a physician which includes the provision of the designated health service." Id.

§ 1395nn(h) (5). Plainly, then, inpatient services constitute a prohibited referral for the furnishing of designated health services, and the district court properly instructed the jury to factor them into the damages calculation.

2.

Tuomey also asserts that the jury's damage award is flawed because the government failed to present sufficient evidence of referrals. Specifically, Tuomey contends that the government did not identify the "referring physician," and thus failed to prove that the alleged false claims came about through a prohibited referral.

The government's proof on this point came in the form of summary evidence and testimony detailing the claims submitted by Tuomey. We agree with the district court that the government's evidence was sufficient to support the jury's verdict. We note also, as did the district court, that "Tuomey was entitled to offer its own expert and its own alternate damages calculations, but elected not to do so." J.A. 4061.

In any case, Tuomey offers no authority to support its argument that the claims must explicitly identify the referring provider. Conversely, several courts have accepted that the "'attending/operating' physician identified in Form UB-92

qualifies as a referring physician.”¹⁶ United States v. Rogan, 459 F. Supp. 2d 692, 713 (N.D. Ill. 2006); see also United States v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002-Orl-31TBS, 2013 WL 6017329, at *10-11 (M.D. Fla. Nov. 13, 2013) (finding that the fact that one of the physicians with whom the hospital has a financial relationship is identified as an “operating” or “attending” physician is sufficient evidence that the physician was also the “referring physician” absent evidence to the contrary). Given the lack of support for Tuomey’s position, we conclude that the jury had sufficient evidence to identify the prohibited referrals.

3.

Tuomey next argues that the district court erroneously assessed the penalty based on the 21,730 UB-92/04 forms Tuomey submitted to Medicare for reimbursement. Instead, Tuomey asserts that the number of false claims should be limited to four Medicare cost reports that it submitted.¹⁷

¹⁶ Form UB-92 (later replaced by Form UB-04) is used by hospitals to submit a claim for reimbursement to Medicare.

¹⁷ Cost reports (CMS-2552) “are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries. . . . Medicare relies upon the hospital cost report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare.” J.A. 68-69 (citing 42 C.F.R. §§ 405.1803, 413.60, 413.64(f)(1)).

Tuomey provides no Stark Law case to support its argument. Rather, it cites to FCA cases where the UB-92/04 forms themselves were not fraudulent, but were submitted as part of an ongoing fraudulent scheme. In those cases, the fraud was consummated only when the cost report was submitted. See United States ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 70-71 (D.D.C. 2007); Visiting Nurse Ass'n of Brooklyn v. Thompson, 378 F. Supp. 2d 75, 99 (E.D.N.Y. 2004).

But even those cases suggest that a UB-92/04 form can constitute a discrete fraudulent claim under the FCA when the government proves that the forms were, in fact, false or fraudulent. See Hockett, 498 F. Supp. 2d at 70-71; Visiting Nurse Ass'n, 378 F. Supp. 2d at 99. This occurs when "the provider knowingly asks the Government to pay amounts it does not owe." United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002).

Here, each time Tuomey submitted to Medicare a UB-92/04 form asking for reimbursement for a prohibited referral, it was knowingly asking the government to pay an amount that, by law, it could not pay. Consequently, we find the district court did not err in finding that each UB-92/04 form constituted a separate claim.

B.

Tuomey also challenges the district court's measure of actual damages. It argues that the true measure is not the sum total of all claims the government paid (as the court instructed the jury), but rather the difference (if any) between the true value of the services provided by Tuomey and what the government actually paid. According to Tuomey, since "there was no evidence that the Government did not get what it paid for[,] . . . there were no actual damages under the FCA." Appellant's Br. at 87. Here again, Tuomey's view of the law is incorrect.

The Stark Law prohibits the government from paying any amount of money for claims submitted in violation of the law. 42 U.S.C. § 1395nn(g)(1). Compliance with the Stark Law is a condition precedent to reimbursement of claims submitted to Medicare. When Tuomey failed to satisfy that condition, the government owed it nothing. United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008).

The Stark Law expresses Congress's judgment that all services provided in violation of that law are medically unnecessary. By reimbursing Tuomey for services that it was legally prohibited from paying, the government has suffered injury equivalent to the full amount of the payments. Cf. United States v. Mackby (Mackby II), 339 F.3d 1013, 1018-19 (9th

Cir. 2003) (finding that the fact that the defendant actually rendered the service billed did not negate the government's injury, as "[d]amages under the FCA flow from the false statement"). In this case, the damage from the false statement came from the payment to an entity that was not entitled to any payment at all. Accordingly, we reject Tuomey's claim of error.¹⁸

C.

Finally, Tuomey argues that the district court's award of \$237,454,195, consisting of damages and a civil penalty, is unconstitutional under the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth Amendment. While the award is substantial, we cannot say that it is unconstitutional.

"The Excessive Fines Clause of the Eighth Amendment prohibits the government from imposing excessive fines as punishment." Korangy v. FDA, 498 F.3d 272, 277 (4th Cir. 2007). "Civil fines serving remedial purposes do not fall within the reach of the Eighth Amendment." Id. But where "a civil sanction 'can only be explained as serving in part to punish,'"

¹⁸ For the same reason, we also reject Tuomey's contention that the district court erred in failing to instruct the jury that the government had to prove that the services received were worth less than what the government paid.

then the fine is subject to the Eighth Amendment.” Id. (quoting Austin v. United States, 509 U.S. 602, 610 (1993)). In such a case, the fine “will be found constitutionally excessive only if it is ‘grossly disproportional to the gravity of [the] offense.’” Id. (alteration in original) (quoting United States v. Bajakajian, 524 U.S. 321, 334, (1998)). We have said, however, that instances in which the penalty prescribed under the FCA is unconstitutionally excessive will be “infrequent.” United States ex rel. Bunk v. Gosselin World Wide Moving, N.V., 741 F.3d 390, 408 (4th Cir. 2013).

By contrast, the Due Process Clause “imposes substantive limits beyond which penalties may not go.” TXO Prod. Corp. v. Alliance Res. Corp., 509 U.S. 443, 453-54 (1993) (internal quotation marks omitted) (Fourteenth Amendment case); Morgan v. Woessner, 997 F.2d 1244, 1255 (9th Cir. 1993) (finding that the Supreme Court’s analysis under the Due Process Clause of the Fourteenth Amendment applies equally under the Fifth Amendment), cited with approval in EEOC v. Fed. Express Corp., 513 F.3d 360, 376 (4th Cir. 2008). Like the Eighth Amendment, the Due Process Clause does not apply to compensatory damage awards. This is because compensatory damages “redress the concrete loss the plaintiff has suffered by reason of the defendant’s wrongful conduct,” and the assessment of the plaintiff’s injury is “essentially a factual determination.” Cooper Indus., 532 U.S.

at 432. On the other hand, punitive damages are "essentially 'private fines' intended to punish the defendant and to deter future wrongdoing." Id. Consequently, there must be "procedural and substantive constitutional limitations on these awards." See State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408, 416 (2003). Thus, the Due Process Clause imposes limits on "grossly excessive" monetary penalties that go beyond what is necessary to vindicate the government's "legitimate interests in punishment and deterrence." BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 562 (1996).

The "FCA imposes damages that are essentially punitive in nature." Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 784 (2000). But the Supreme Court has also noted that the treble damages provision of the statute has a compensatory aspect, in that they account for the fact that some amount of money beyond actual damages is "necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims." Cook Cnty., Ill. v. United States ex rel. Chandler, 538 U.S. 119, 130 (2003). Additionally, the provision allows the government to recover some measure of the amount it must pay to compensate relators in qui tam actions. Id.; see also 31 U.S.C. § 3730(d) ("If the Government proceeds with an action brought by [a relator, the relator] shall . . . receive at least 15 percent

but not more than 25 percent of the proceeds of the action or settlement of the claim"). On the other hand, the civil penalty is completely punitive. United States v. Mackby (Mackby I), 261 F.3d 821, 830 (9th Cir. 2001).

The Supreme Court has instructed courts to consider three guideposts when reviewing punitive damages awards under the Due Process Clause: "(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases."¹⁹ State Farm, 538 U.S. at 418. There is no reason to believe that the Court's "approach to punitive damages under the Fifth Amendment would differ dramatically from analysis under the Excessive Fines Clause." Rogan, 517 F.3d at 454.

The degree of reprehensibility of the defendant's conduct is "[p]erhaps the most important indicium of the reasonableness of a punitive damages award." Gore, 517 U.S. at 575. Of

¹⁹ Because the FCA's civil penalty and treble damages provisions are Congressional mandates, we believe this final factor is not instructive here. Indeed, to the extent that the district court exercised any discretion at all, it did so by imposing the statutory minimum civil penalty for each fraudulent claim.

course, in this case the damages and penalties assessed against Tuomey are congressionally prescribed. 31 U.S.C. § 3729(a)(1). As we have previously stated, the Stark Law expresses Congress's judgment of the reprehensibility of the conduct at issue by deeming services provided in violation of the law worthless. And "[t]he fact . . . that Congress provided for treble damages and an automatic civil monetary penalty per false claim shows that Congress believed that making a false claim to the government is a serious offense." Mackby II, 339 F.3d at 1018; cf. Rogan, 517 F.3d 454 ("[O]ne would think that a fine expressly authorized by statute could be higher than a penalty selected ad hoc by a jury.").

In addition, the Supreme Court has directed courts to evaluate the degree of reprehensibility of the defendant's conduct by considering whether:

the harm caused was physical as opposed to economic; the tortious conduct evinced an indifference or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident.

State Farm, 538 U.S. at 419. While Tuomey's conduct in this case does not implicate the first three factors, we think the last two are relevant here. See Saunders v. Branch Banking & Trust Co. of Va., 526 F.3d 142, 153 (4th Cir. 2008) (finding

that even the presence of a single State Farm factor "can provide justification for a substantial award of punitive damages").

Clearly, Tuomey's conduct "involved repeated actions," State Farm, 538 U.S. at 419, as it submitted 21,730 false claims. Thus, while the penalty is certainly severe, it is meant to reflect the sheer breadth of the fraud Tuomey perpetrated upon the federal government. Bunk, 741 F.3d at 407-08 (explaining that the court was comfortable assessing high civil penalties in FCA actions involving a large number of claims). As we have said, "[w]hen an enormous public undertaking spawns a fraud of comparable breadth [high penalties] help[] to ensure what we reiterate is the primary purpose of the FCA: making the government completely whole." Id. Substantial penalties also serve as a powerful mechanism to dissuade such a massive course of fraudulent conduct. See id. at 408. And the government has "a strong interest in preventing fraud" because "[f]raudulent claims make the administration of Medicare more difficult, and widespread fraud would undermine public confidence in the system." Mackby II, 339 F.3d at 1019.

Nor were Tuomey's actions in this case the result of a "mere accident." State Farm, 538 U.S. at 419. Rather, the jury determined that Tuomey submitted false claims for Medicare reimbursement "knowingly," that is, with actual knowledge, in

deliberate ignorance, or with reckless disregard that the claims violated the Stark Law. Under the circumstances, we agree with the government that "strong medicine is required to cure the defendant's disrespect for the law." Gore, 517 U.S. at 577.

Next, we consider the disparity between actual harm and the punitive damages award. Specifically, we compare the actual damages assessed against Tuomey to the civil penalty and the portion of treble damages that can be considered punitive. Here, we can properly regard the entire civil penalty, \$119,515,000, as punitive. On the other hand, the actual damages of \$39,313,065 are entirely compensatory. As discussed above, the additional sum of \$78,626,130 resulting from the trebling of actual damages is a hybrid of compensatory and punitive damages.

Although the Supreme Court has not told us where to draw the line, see Chandler, 538 U.S. at 131, we may safely assume that the portion of the trebled award allocated to the relator is compensatory. See id. Assuming further that Drakeford receives the minimum amount allotted by the statute--that is fifteen percent of the total recovery--the relator would be entitled to \$11,793,920 of the trebled award, leaving \$66,832,210 to be allocated to punitive damages. By this calculation, the portion of damages that is compensatory is \$51,106,985 and the \$186,347,210 balance is punitive.

While the Court has been reluctant to fix a bright-line ratio that punitive damages cannot exceed for purposes of the Due Process Clause, it has suggested that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety." State Farm, 538 U.S. at 425. Here, the ratio of punitive damages to compensatory damages is approximately 3.6-to-1, which falls just under the ratio the Court deems constitutionally suspect.²⁰ We therefore conclude that the damages award is constitutional under the Fifth and Eighth Amendments.

V.

Finally, we do not discount the concerns raised by our concurring colleague regarding the result in this case. But having no found no cause to upset the jury's verdict in this case and no constitutional error, it is for Congress to consider whether changes to the Stark Law's reach are in order.

AFFIRMED

²⁰ The government contends that the ratio between the penalty awarded and the actual damages (after accounting for the relator's recovery) may be as low as 2-to-1 or even 1-to-1. This calculation, however, ignores the treble damages award, a portion of which we consider to be punitive.

WYNN, Circuit Judge, concurring:

Because Tuomey opened the door to the admission of Kevin McAnaney's testimony by asserting an advice of counsel defense, and because I cannot say, based on the record before me, that no rational jury could have determined that Tuomey violated both the Stark Law and the False Claims Act, I concur in the outcome today.

But I write separately to emphasize the troubling picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.

I.

Regarding the issue of whether the district court correctly granted a new trial, we review such a decision for abuse of discretion. Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998). Similarly, we "review a trial court's rulings on the admissibility of evidence for abuse of discretion," and we will overturn such a ruling only if it is "arbitrary and irrational." United States v. Cole, 631 F.3d 146, 153 (4th Cir. 2011) (quotation marks and citation omitted).

A.

Judge Perry, who presided over the first trial, excluded McAnaney's testimony pursuant to Evidence Rule 408, which can be

used to exclude evidence of settlement negotiations. Under Rule 408, "conduct or a statement made during compromise negotiations about [a disputed] claim" is generally inadmissible when used to "prove or disprove the validity or amount of a disputed claim." Fed. R. Evid. 408(a).

It is unclear to me that the district court abused its discretion in determining that McAnaney's testimony could be excluded under Rule 408. In his deposition testimony, McAnaney described himself as "a tie breaker" who was jointly hired by Drakeford and Tuomey when they could not agree about whether the contracts violated the Stark Law—arguably a disputed claim. J.A. 139-41. Tuomey's and Drakeford's dispute about the legality of the contracts reached impasse and ended in Drakeford acting as a relator of this qui tam action only three months later. Had Drakeford and Tuomey been able to reach an agreement, Drakeford presumably would not have filed this suit, in which the government, having intervened, now stands in Drakeford's shoes.

Rule 408's exclusionary provision applies where a "dispute or a difference of opinion exists," not just "when discussions crystallize to the point of threatened litigation." Affiliated Mfrs., Inc. v. Aluminum Co. of Am., 56 F.3d 521, 527 (3d Cir. 1995). When viewed thusly, it is hard to say that Judge Perry

acted either arbitrarily or irrationally in deeming McAnaney's testimony excludable.

Crucially, however, evidence subject to exclusion under Rule 408 is so excludable "only if the evidence is offered to prove either liability for or invalidity of a claim or its amount;" otherwise, it may come in. Bituminous Const., Inc. v. Rucker Enterprises, Inc., 816 F.2d 965, 968 (4th Cir. 1987) (emphasis added); Fed. R. Evid. 408(b) ("The court may admit this evidence for another purpose."). Stated differently, "[s]ince the rule excludes only when the purpose is proving the validity or invalidity of the claim or its amount, an offer for another purpose is not within the rule." 2-408 Weinstein's Fed. Evid. § 408.08 (quotation marks and citation omitted). Therefore, if the McAnaney evidence was admissible for a purpose beyond the validity or amount of a disputed claim, Rule 408 would provide no basis for barring it wholesale from the first trial.

B.

The government argues, among other things, that the McAnaney evidence went to the heart of an issue wholly beyond the scope of Rule 408's limited exclusionary ambit—namely, Tuomey's advice of counsel defense. With this, I must agree.

As explained by a district court in this Circuit in the context of a False Claims Act fraud claim, "good faith reliance

on the advice of counsel may contradict any suggestion that a [defendant] 'knowingly' submitted a false claim." United States v. Newport News Shipbuilding, Inc., 276 F. Supp. 2d 539, 565 (E.D. Va. 2003). "[I]f a [defendant] seeks the advice of counsel in good faith, provides full and accurate information, receives advice which can be reasonably relied upon, and, in turn, faithfully follows that advice, it cannot be said that the defendant 'knowingly' submitted false information or acted with deliberate ignorance or reckless disregard of its falsity, even if that advice turns out in fact to be false." Id. See also, e.g., United States v. Butler, 211 F.3d 826, 833 (4th Cir. 2000) (identifying the elements of the advice of counsel defense as "(a) full disclosure of all pertinent facts to [a lawyer], and (b) good faith reliance on the [lawyer]'s advice").

When a party raises an advice of counsel defense, however, all advice on the pertinent topic becomes fair game. "It has . . . become established that if a party interjects the 'advice of counsel' as an essential element of a claim or defense," then "all advice received concerning the same subject matter" is discoverable, not subject to protection by the attorney-client privilege, and, by logical extension, admissible at trial. 1 McCormick On Evid. § 93 (7th ed. 2013). See also, e.g., In re EchoStar Commc'ns Corp., 448 F.3d 1294, 1299 (Fed. Cir. 2006) ("Once a party announces that it will rely on advice of counsel

. . . the attorney-client privilege is waived. The widely applied standard for determining the scope . . . is that the waiver applies to all other communications relating to the same subject matter. . . . Thus, when EchoStar chose to rely on the advice of in-house counsel, it waived the attorney-client privilege with regard to any attorney-client communications relating to the same subject matter, including communications with counsel other than in-house counsel, which would include" the advice of outside counsel.) (quotation marks and citation omitted).

Here, there can be no doubt that Tuomey pressed an advice of counsel defense. Tuomey argued to the first jury, for example, that "[t]he lawyers were the ones running the show . . . All Tuomey did was accept their recommendations and vote on them if they thought that it was something that would be good for the hospital. Advice of counsel is a very, very good defense. It is one that the law recognizes, and it is one that . . . fits perfectly in this situation." Trial I, Transcript for Mar. 25, 2010, at 1986.

Further, the district court instructed the jury on the advice of counsel defense, making clear that it provided a vehicle for absolving Tuomey of False Claims Act liability. The court instructed, among other things, that "the defendant has asserted an affirmative defense of advice of counsel to the

United States' allegation that it acted in violation of the False Claims Act. An affirmative defense is an argument that, if true, will defeat the government's claim." Trial I, Transcript for Mar. 26, 2010, at 2098-99. Regarding what Tuomey needed to show to succeed with that defense, Judge Perry instructed that "in order for the defendant to prevail on its affirmative defense of advice of counsel, Tuomey must prove the following: One, that the advice was sought in good faith; two, that Tuomey provided full and accurate information to the attorney; three, the advice could be reasonably relied upon; and, four, Tuomey faithfully followed the attorney's advice."

Id.

Having put the advice it got from its lawyers squarely at issue, Tuomey should not have been permitted to cherry-pick which advice of counsel the jury was permitted to hear. Instead, the jury should have been allowed to consider all the advice of all Tuomey's counsel—including McAnaney.

The record makes clear that, whatever else McAnaney's assessment was, it was also advice of counsel. McAnaney's engagement letter to Tuomey and Drakeford, who had hired him jointly, stated that McAnaney, a lawyer, had been "retained" to "review and advise" the parties "with respect to a proposed business relationship." J.A. 145. McAnaney committed to being guided by the parties' "instructions in carrying out the

representation" and reporting to the parties his "conclusions" and "any potential compliance issues." Id. In other words, McAnaney was Tuomey's counsel, and he advised Tuomey about the contracts at the heart of this case.

The record makes similarly clear that Tuomey did not follow McAnaney's advice. McAnaney advised Tuomey that the proposed contracts raised significant "red flags" under the Stark Law. J.A. 2054. McAnaney advised that Tuomey would have difficulty persuading the government that the contracts did not compensate the physicians in excess of fair market value. And McAnaney warned Tuomey that the contracts presented "an easy case to prosecute" for the government. J.A. 2078. Rather than heed this advice and back away from the contracts, however, Tuomey told McAnaney not to put his conclusions in writing and ended his engagement.

Allowing McAnaney's testimony into evidence to show the advice he gave in light of Tuomey's advice of counsel defense would have been outside of Rule 408's limited exclusionary ambit. In other words, by pressing an advice of counsel defense, Tuomey itself opened the door for McAnaney's testimony to come in, even if it otherwise might have been excludable under Rule 408. See Fed. R. Evid. 408(b). Despite this, the district court barred McAnaney's testimony wholesale.

In keeping McAnaney out of the first trial, the district court prevented the jury from getting the full picture of what advice Tuomey had gotten from counsel. Tuomey told the jury that “[t]he lawyers were the ones running the show . . . All Tuomey did was accept their recommendations.” Trial I, Transcript for Mar. 25, 2010, at 1986. But the government was effectively prevented from showing that Tuomey had gotten conflicting recommendations from its different counsel, picked its preferred advice, and discarded the rest. It is hard to imagine that this constituted anything other than a prejudicial abuse of discretion. Cf. Rodriguez-Garcia v. Municipality of Caguas, 495 F.3d 1 (1st Cir. 2007) (reversing because erroneous Rule 408 ruling hamstrung plaintiff’s ability to show elements of claim).

In sum, in allowing Tuomey to press its advice of counsel defense and giving the jury an advice of counsel instruction yet preventing the jury from hearing all the advice that Tuomey got, the district court abused its discretion and prejudiced the government. This error alone was grave enough to warrant a new trial. Accordingly, I, too, conclude that Judge Perry’s decision to grant a new trial must be upheld.

II.

Moving beyond the district court's decision to grant a new trial, I agree with the majority that the jury's determination that Tuomey violated both the Stark Law and the False Claims Act must stand. Our standard of review at this juncture is a highly deferential one, "accord[ing] the utmost respect to jury verdicts" and "constraining" us to affirm so long as the record contains "sufficient evidence for a reasonable jury" to have returned the verdict it did. Lack v. Wal-Mart Stores, Inc., 240 F.3d 255, 259 (4th Cir. 2001). After careful review of the record, I cannot conclude that no reasonable jury could have reached the verdict before us.

Nevertheless, I am troubled by the picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.

A.

The Stark Law is, at its core, a prohibition on self-referrals, barring doctors from referring patients for certain services to entities in which the doctors (or their immediate family members) have a financial interest, unless an exception applies. Patrick A. Sutton, The Stark Law in Retrospect, 20 Annals Health L. 15, 25-26 (2011). Further, entities providing

the pertinent services are prohibited from billing Medicare or Medicaid pursuant to such a prohibited referral. Id.

"The Stark Law is a strict liability statute so it is immaterial whether one intended to violate the law; an inadvertent violation can trigger liability." Paula Tironi, The "Stark" Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?, 19 Annals Health L. 235, 237-38 (2010). Individuals and entities that violate the Stark Law can be subject to severe monetary penalties and exclusion from federal health care programs. Id. These "steep civil sanctions and program exclusions may be ruinous. Health care providers are open to extensive liability, their financial security resting uneasily upon a combination of their attorneys' wits [and] prosecutorial discretion."

Jo-Ellyn Sakowitz Klein, The Stark Laws: Conquering Physician Conflicts of Interest?, 87 Geo. L.J. 499, 503-04 (1998).

Despite attempts to establish "bright line" rules so that physicians and healthcare entities could "ensure compliance and minimize . . . costs," 66 Fed. Reg. 856, 860 (Jan. 4, 2001), the Stark Law has proved challenging to understand and comply with. Indeed, "[t]he Stark law is infamous among health care lawyers and their clients for being complicated, confusing and counter-intuitive; for producing results that defy common sense, and sometimes elevating form over substance. Ironically, the Stark

law was actually intended to simplify life by creating 'bright lines' between what would be permitted and what would be disallowed, and creating certainty by removing intent from the equation." Charles B. Oppenheim, The Stark Law: Comprehensive Analysis + Practical Guide 1 (AHLA 5th ed. 2014). Some of the invective used to describe the Stark law even borders on lyrical: "ambiguous[,] arcane[,] and very vague;" and "heaps of words in barely decipherable bureaucratese." Steven D. Wales, The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals, 27 Law & Psychol. Rev. 1, 22-23 (2003) (quotation marks and citations omitted).

Given this complexity and the strict liability nature of the statute, a Stark Law "compliance program can help a physician or [] entity prove good faith and obtain leniency in the event of a violation; however, the Stark Law's complexity and frequent revisions make it difficult for physicians and entities to develop and implement such programs." Tironi, supra at 238. Against this problematic backdrop, the availability of an advice of counsel defense should perhaps be especially robust in Stark Law cases prosecuted under the False Claims Act.

B.

The False Claims Act discourages fraud against the federal government by imposing liability on "any person who . . . knowingly presents, or causes to be presented, a false or

fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). The False Claims Act is meant "to indemnify the government . . . against losses caused by a defendant's fraud," Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citing United States. ex rel. Marcus v. Hess, 317 U.S. 537, 549, 551-52 (1943)), as opposed to a defendant's mistake.

Accordingly, a defendant may skirt False Claims Act liability by showing good faith reliance on the advice of counsel. As the majority opinion recognizes, in fraud cases, "'[i]f in good faith reliance upon legal advice given him by a lawyer to whom he has made full disclosure of the facts, one engages in a course of conduct later found to be illegal,' the trier of fact may conclude that the conduct was innocent because "'the guilty mind' was absent." Ante at 30-31 (quoting United States v. Painter, 314 F.2d 939, 943 (4th Cir. 1963)).

In the context of the Stark Law, it is easy to see how even diligent counsel could wind up giving clients incorrect advice. Between the law's being amended to have a broader scope but then narrowed with various exceptions, along with the promulgation and amendment of copious associated rules and regulations, "the Stark Law bec[ame] a classic example of a moving target. For lawyers, who must depend on the predictability of the law when they give counsel to their clients, such unpredictability [i]s an unusually heavy burden." Wales, supra at 21.

In this case, there can be no doubt that Tuomey sought and followed the advice of its long-time counsel, Nexsen Pruet. Nexsen Pruet drafted and approved the contracts at the heart of this litigation. Tuomey and Nexsen Pruet consulted with others, including the nation's largest healthcare law firm and a national consulting firm with expertise in physician compensation. Those experts, too, signed off on the arrangements (though the parties dispute whether Tuomey had shared all pertinent information for purposes of these additional assessments).

Nevertheless, as the majority opinion notes, "a reasonable jury could have concluded that Tuomey was . . . no longer acting in good faith reliance on the advice of its counsel when it refused to give full consideration to McAnaney's negative assessment of the" contracts. Id. at 32. As already explained, McAnaney, the former Chief of the Industry Guidance Branch at the Department of Health and Human Services' Office of Counsel to the Inspector General, also served as Tuomey's counsel. And he advised Tuomey that the proposed arrangements raised significant red flags and may well be unlawful. Had Tuomey followed McAnaney's advice, it likely would have faced no lawsuit in which to raise an advice of counsel, or any other, defense.

III.

This case is troubling. It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act. Yet, the district court did not abuse its discretion when it granted a new trial and the jury did not act irrationally when it determined that Tuomey violated both the Stark Law and the False Claims Act. Accordingly, I must concur in the outcome reached by the majority.